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Percutaneous balloon dilatation of the atrial septum: immediate and midterm results

B D Thanopoulos, D Georgakopoulos, G S Tsaousis, S Simeunovic

Abstract

***Objectives*—To assess the effectiveness of atrial septostomy by percutaneous balloon dilatation in patients with congenital heart defects or primary pulmonary hypertension.**

***Patients and design*—Twenty three patients (15 boys, eight girls; aged 10 days to 10 years; 17 with congenital heart defects and six with primary pulmonary hypertension), all haemodynamically unstable under optimal medical treatment, underwent atrial septostomy by percutaneous balloon dilatation.**

***Interventions*—The balloon catheter entered the left atrium through a patent foramen ovale (n = 14) or via transseptal puncture in cases with an intact atrial septum (n = 9). The size of the balloons used ranged from 13 to 18 mm.**

***Results*—There were no complications. The interatrial communication (mm) increased (P < 0·05) after dilatation and remained unchanged (P = NS) during a 16·6 (13·8) month follow up (2 (1·7) *v* 8·8 (1·4) *v* 8·2 (1·1), respectively). Transatrial gradient (mm Hg) fell and arterial oxygenation (%) improved both in patients with transposition (6·3 (0·8) *v* 0·8 (1)(P = 0·0001) and 40·6 (4·2) *v* 76·5 (4·8) (P = 0·0001), respectively) and in those with mitral atresia (13·4 (1·9) *v* 2 (1·4) (P = 0·0001) and 77·1 (3·9) *v* 81·5 (4·2) (P = 0·008), respectively). There were two failures, one early and one late, both in the group of patients with mitral atresia or stenosis. A decrease in arterial oxygenation (94·8 (1·5) *v* 83 (2·4), P = 0·004) and an increase in left atrial pressure (6·8 (0·9) *v* 8·3 (1·2), P = 0·02) and cardiac index (2·3 (0·2) *v* 3·1 (0·2) l/min/m², P = 0·002) was observed in patients with primary pulmonary hypertension.**

***Conclusions*—Percutaneous balloon dilatation is an effective and safe procedure for creating an adequate interatrial communication that can be used as an alternative to blade septostomy.**

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Keywords: atrial septostomy; balloon dilatation; congenital heart defects; primary pulmonary hypertension

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Blade atrial septostomy was first performed by Park *et al*[1] in the 1970s. They developed and used a catheter equipped with a knife blade at its tip. This method has been used to create an atrial septal defect in order to improve haemodynamics in cases in which a classic balloon atrial septostomy was impossible or inadequate for anatomical reasons.[2] Although blade atrial septostomy has had good results and its value has been well established,[3,4] it is not free of complications, some of which may be fatal,[5] especially in patients with a small left atrium.[6]

Atrial septostomy by percutaneous balloon dilatation using valvuloplasty balloons has been used in some patients as an alternative to blade atrial septostomy with encouraging initial results. The purpose of this study was to report the immediate and midterm results from 23 consecutive patients in whom an atrial septal defect was created or enlarged by percutaneous balloon dilatation of the atrial septum.

Patients and methods

PATIENTS

Twenty three patients (15 male and eight female; age 10 days to 10 years, median four months) underwent percutaneous balloon dilatation of the atrial septum at our hospital from May 1991 to July 1995. The patients' demographic, echocardiographic, and haemodynamic data are shown in tables 1 and 2. Seven patients had simple transposition of the great arteries (five with intact ventricular septum and two with a small ventricular septal defect) and either absent or insufficient interatrial communication resulting in poor intercirculatory mixing of blood and severe arterial hypoxaemia. Nine patients had complex congenital heart defects with mitral atresia physiology—that is, either atresia or severe stenosis of the left atrioventricular valve. The decision to perform percutaneous balloon dilatation of the atrial septum in these patients was made on the basis of clinical findings, a chest *x* ray indicative of passive pulmonary congestion, and echocardiographic evidence of either absent or small interatrial opening with the septum bulging to the right side. One patient had tricuspid atresia and cardiac output depended on a right atrial to left atrial shunt. Six patients had primary pulmonary hypertension with symptoms ranging from progressive fatigue and dyspnoea to syncope and cyanotic spells despite treatment with diuretics and nifedipine and the nightly administration of oxygen at home (table 2). All patients had evidence of a thickened atrial septum on cross sectional echocardiography, which was associated with a low success rate when classic balloon atrial septostomy was used in an earlier

Table 1 Patients' demographics, echocardiographic, haemodynamic data and outcome

				Arterial O^2 saturation (%)		Interatrial communication (mm)			Transatrial gradient (mm Hg)			
Case	Diagnosis	Age	BSA	Pre	Post	Pre	Post	F-U	Pre	Post	Outcome (Age at op)	Follow up (mnth)
1	TGA	10 day	0·21	36	73	0	9	8	—	—	S (6 mnth)	6
2	TGA	2 mnth	0·26	48	73	4	9	9	5	1	M 7 mnth)	5
3	TGA	50 day	0·24	39	83	3	10	9	7	0	S (9 mnth)	7
4	TGA	2 mnth	0·25	40	70	3	8	8	7	2	S (7 mnth)	4
5	TGA	3 mnth	0·31	41	77	3	9	9	6	0	S (9 mnth)	6
6	TGA	3 mnth*	0·29	43	67	2	8·5	8	7	2	S (6 mnth)	3
7	TGA	4 mnth*	0·33	37	83	3	11	9	6	0	S (9 mnth)	5
8	MAP	2 mnth	0·26	75	81	0	10	11	—	—	BCA (20 mnth)	32
9	MAP	3 mnth	0·31	79	79	4	8	—	12	0	—	—
10	MAP	14 mnth	0·47	76	79	5	8	5‡	12	3	Doing well	8
11	MAP	8 mnth	0·38	74	79	0	11	9	—	—	BT (18 mnth)	8
12	MAP	16 mnth	0·49	80	80	3	9·5	9	13	2	BCA (6 mnth)	36
13	MAP	4 mnth	0·33	70	76	3	10·00	10	13	1	BT (6 mnth)	26
14	MAP	4 mnth	0·34	82	88	3	5†	—	—	—	—	—
15	MAP	32 mnth	0·56	78	88	4	10	10	17	2	Much improved	12
16	MAP	5 mnth	0·34	80	84	3	9	8	15	4	BT (16 mnth)	28
17	TA	3 mnth	0·3	58	72	3	9	8	4	1	BT (4 mnth)	30
18	PPH	28 mnth	0·55	95	86	0	8	8	—	—	Improved	48
19	PPH	6 yr	0·75	96	84	0	10	9	—	—	Improved	36
20	PPH	8 yr	0·92	95	79	0	10	10	—	—	Improved	26
21	PPH	3 yr	0·6	95	83	0	8	8	—	—	Improved	6
22	PPH	7·5 yr	0·89	96	84	0	7	7	—	—	Improved	4
23	PPH	10 yr	1·1	92	82	0	9	9	—	—	Improved	13

TGA, transposition of the great arteries; MAP, mitral atresia physiology; TA, tricuspid atresia; PPH, primary pulmonary hypertension; BSA, body surface area; F U, follow up; op, operation; S, senning operation; M, mustard operation; BCA, bicaval anastomosis; BT, Blalock-Taussig shunt.
*Small VSD.
†blade septostomy.
‡repeat procedure.

Table 2 Clinical and haemodynamic data of patients with primary pulmonary hypertension

		mRAP (mm Hg)		mLAP (mm Hg)		Cardiac index ($l/min/m^2$)		PAR ($Units/m^2$)	
Case	Symptoms	Pre	Post	Pre	Post	Pre	Post	Pre	Post
1	Cyanotic episodes	7	7	6	8	2·3	3·1	22	23
2	Syncope, fatigue	10	8	6	7	2·4	3·3	17	19
3	Syncope, fatigue	12	10	8	9	2·5	3·4	24	22
4	Fatigue, cyanotic episodes	9	8	6	7	2·4	3·0	21	22
5	Fatigue, dyspnoea	13	10	7	9	2·3	3·0	21	24
6	Syncope, severe dyspnoea	16	11	8	10	2·0	3·2	28	27

mRAP, mean right atrial pressure; mLAP, mean left atrial pressure; PAR, pulmonary arteriolar resistance.

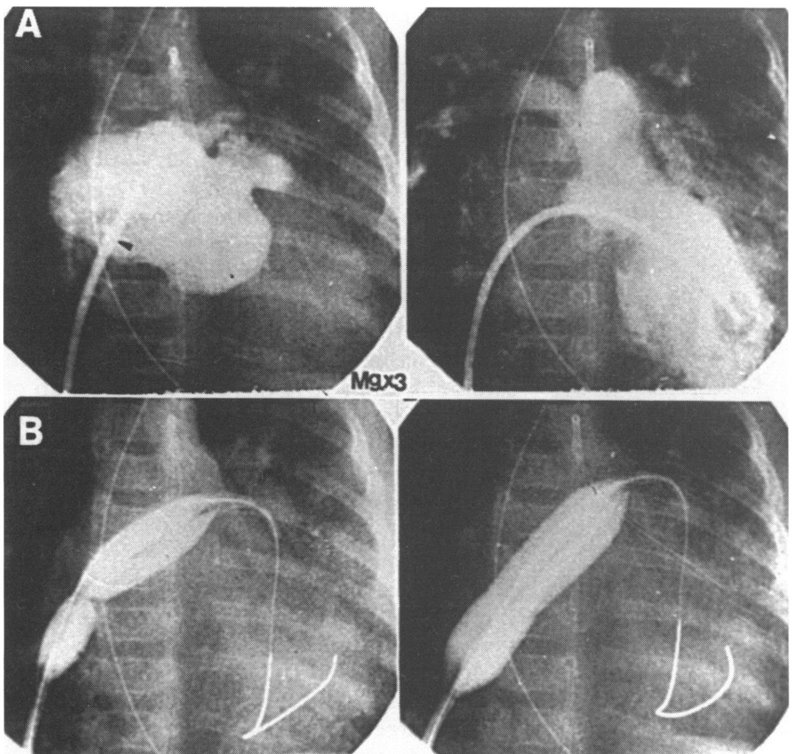

Figure 1 Percutaneous balloon dilatation of the atrial septum in a three month old infant with D-transposition of the great arteries and small (closing) ventricular septal defect. (A) Left atrial injection and left ventriculography, through a Mullins sheath and a Berman catheter, respectively. (B) Balloon changes during the procedure (MgX3, image magnification × 3).

study[2]; balloon dilatation had not previously been attempted in such patients.

TECHNIQUE

The procedure was performed in the cardiac catheterisation laboratory under fluoroscopic guidance. General anaesthesia was used in two infants, whereas procedures in all other cases were performed under local anaesthesia with 1% lignocaine. After percutaneous catheterisation of the right femoral vein, right and left (when a patent foramen ovale was present) atrial pressures and saturations were measured using a 4F or 5F Multipurpose catheter. An arterial blood sample was also taken for pH, pO_2, and oxygen saturation measurements. In nine cases with an intact atrial septum (one with transposition of the great arteries, two with mitral atresia or stenosis, and all six with primary pulmonary hypertension) a transseptal puncture by the Mullins technique was performed (fig 1A).[7] Subsequently, the catheter placed in the left atrium was exchanged over a 0·035 or 0·038 inch guidewire for a balloon dilatation catheter. All the procedures were performed with a standard length (3 cm) balloon. This was sufficiently long for the balloon to be stabilised without risk of placing either the proximal or distal portion of the balloon in the inferior vena cava, pulmonary veins, or across the left atrioventricular valve (fig 1B). The balloon diameters were 13 mm in newborns, 15 mm in infants, and 18 mm in older children (10 trefoil balloons (Meier-Shneider) and 13 single balloons (Mansfield)). In the six patients with primary pulmonary hypertension the initial dilatation was performed with a 13 mm balloon and after reassessment of haemodynamics further dilatations with 15 mm or 18 mm balloons were performed, aimed at producing a systemic arterial oxygen saturation of 80–85%. The dilatation procedure followed previously described protocols.[8-13] Atrial pressures and saturations as well systemic arterial oxygen saturation were remeasured after dilatation. The size of the patent foramen ovale, if present, and the size of the created interatrial communication were assessed with cross sectional echocardiography and colour flow imaging. Cardiac output in patients with primary pulmonary hypertension was measured by the thermodilution method before septostomy and by the indirect Fick principle after septostomy, using the Lafarge and Miettinen tables of assumed oxygen consumption.[14]

FOLLOW UP

One patient (case 9) was lost to follow up, and the patient in whom a blade septostomy was performed was not included in the follow up study. The remaining 21 were followed for a mean period of 16·6 (13·8) months (range three to 48 months). Repeat evaluation included a complete physical examination; electrocardiogram; chest x ray; and M mode, cross sectional, and Doppler echocardiography.

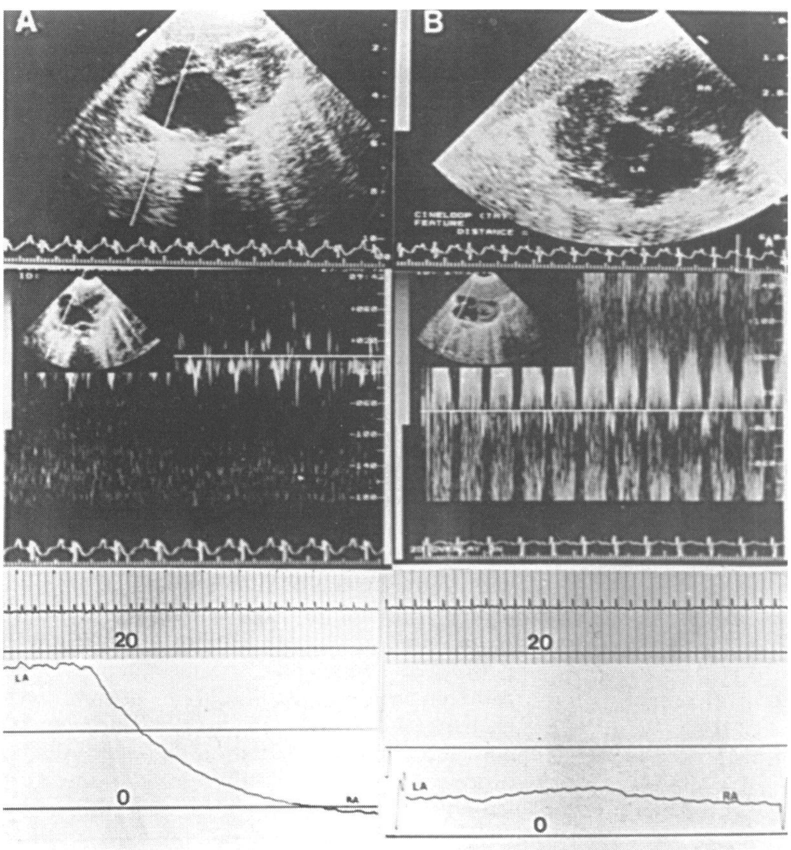

Figure 2 Cross sectional echocardiogram, pulse wave Doppler, and pull-back pressure tracing from right to left atrium before (A) and after (B) initial balloon dilatation in an infant eight months old with univentricular heart, pulmonary stenosis, and severe stenosis of the left atrioventricular valve (RA, right atrium; LA, left atrium; D, atrial septal defect).

STATISTICAL ANALYSIS

Values are presented as mean (SD). Intragroup comparison of continuous variables was performed using Student's paired t test or analysis of variance for repeat measurements as appropiate. A P value $< 0{\cdot}05$ was regarded as statistically significant.

Results

There were no complications related to the procedure. There was one early and one late failure. The early failure occurred in a patient with mitral atresia or stenosis (case 14), in whom the dilatation was unsuccessful and a blade septostomy using the Park blade catheter was employed during the same procedure. The late failure occurred in a patient with mitral atresia or stenosis (case 10), in whom a decrease in the size of the communication led to repeat dilatation (see below).

SIZE OF INTERATRIAL COMMUNICATION

Balloon atrial dilatation was associated with a significant increase in the interatrial communication (preprocedural 2 (1·7) mm (range 0 mm to 5 mm); postprocedural 8·8 (1·4) mm (range 5 to 11 mm), P < 0·05). Postprocedural interatrial communication was not significantly different in patients with an intact septum and those with a non-intact septum before the procedure (8·4 (1·3) mm v 9·1 (1·6) mm respectively, P = NS). A postprocedural right to left shunt could be detected by colour Doppler in patients with primary hypertension and tricuspid atresia.

ARTERIAL SATURATION

The mean saturation in the transposition group before septostomy was 40·6 (4·2)% (range 36% to 48%) and increased to 76·5 (4·8)% (range 67% to 83%) (P = 0·0001) after the procedure. The corresponding mean saturation values in the mitral atresia group were 77·1 (3·9)% (range 69% to 82%) and 81·5 (4·2)% (range 76% to 88%) (P = 0·008), respectively. The patient with tricuspid atresia had an increase in arterial oxygen saturation from 58% to 72%. In the group of patients with primary pulmonary hypertension the arterial saturation decreased (P = 0·004) from 94·8 (1·5)% (range 92% to 96%) to 83 (2·4)% (range 79% to 86%) after septostomy.

HAEMODYNAMICS

Transatrial gradient fell from 6·3 (0·8) mm Hg to 0·8 (1) mm Hg (P = 0·0001) in transposition patients and from 13·4 (1·9) mm Hg to 2 (1·4) mm Hg (P = 0·0001) in patients with mitral atresia or stenosis (fig 2A and B). A total of three patients in those two groups had an intact interatrial septum and needed a transseptal puncture. In these cases the transatrial gradient was not measured because it was not possible to do a pull-back measurement. The same applied to the group of six patients with primary pulmonary hypertension. Table

2 shows the haemodynamic results of this group. Mean right atrial pressure decreased slightly but not significantly (P = NS) from 11·3 (3·5) mm Hg (range 7 to 17 mm Hg) before to 9 (1·5) mm Hg (range 7 to 77 mm Hg) immediately after the procedure, whereas left atrial pressure increased from 6·8 (0·9) mm Hg (range 6 to 8 mm Hg) to 8·3 (1·2) mm Hg (range 7 to 10 mm Hg) (P = 0·02) and cardiac index increased from 2·3 (0·2) l/min/m^2 to 3·1 (0·2) l/min/m^2 (P = 0·002). Pulmonary arteriolar resistance, as expected, was not affected by balloon atrial septostomy (preprocedural 22·8 (3·8) units/m^2; postprocedural 22·8 (2·7) units/m^2; P = NS). The patient with tricuspid atresia had a predilatation interatrial gradient of 4 mm Hg, which fell to 1 mm Hg postdilatation.

FOLLOW UP

The mean diameter of the interatrial communication at follow up was not significantly different from that obtained immediately after the procedure (8·8 (1·4) mm *v* 8·2 (1·1) mm, respectively (P = NS)). Moreover, the mean diameter of interatrial communication at follow up was not significantly different in patients with an intact or a non-intact septum before the procedure (8·4 (1·3) mm *v* 9·1 (1·6) mm, respectively, P = NS).

There was one patient in the mitral atresia/stenosis group (case 10) in whom the size of the communication had decreased to its preseptostomy value (5 mm) eight months after the initial procedure. Echocardiography in this patient showed signs of left atrial dilatation with the interatrial septum bulging to the right. As there was also some degree of pulmonary congestion on the chest *x* ray it was decided to repeat the procedure with a 18 mm balloon instead of the 15 mm which was used the first time. The transatrial pressure gradient fell from 10 to 2 mm Hg and the size of the communication increased from 5 to 9 mm. The arterial oxygen saturation increased from 78% to 83%. At the last follow up, one month after the second dilatation, the patient was doing well and the interatrial communication as measured at echocardiography was 9 mm. All patients with primary pulmonary hypertension showed a significant improvement in symptoms and had no further syncopal episodes; they showed a steady improvement in exercise tolerance. Table 1 shows the outcome in patients during the follow up period.

Discussion

Some forms of congenital heart disease are not compatible with survival in the absence of an interatrial communication. Most important of these is transposition of the great arteries with intact ventricular septum or small ventricular septal defect producing inadequate mixing. An adequate interatrial communication has also been shown to palliate tricuspid atresia,[15] pulmonary atresia with intact ventricular septum,[16] mitral atresia,[17] and recently primary pulmonary hypertension.[18]

The introduction of balloon atrial septostomy has greatly improved the prognosis of patients with transposition of the great arteries; three month survival has increased from 20% to 85%.[19] But beyond the neonatal period, the lower margin of the patent foramen ovale is thick and muscular[20] and cannot be ruptured by Rashkind's balloon, leading to failure of this technique in older infants and children.[21] To circumvent this problem, Park *et al*[1] developed a catheter with a built-in retractable blade to cut the lower margin of the foramen ovale. Although this technique has had good success rates, ranging from 70% to 90%,[3] it can cause fatal complications especially when the left atrium is small.[5 6]

Atrial septostomy by percutaneous balloon dilatation was first described in 1986 by Mitchell *et al*[22] in an experimental model. In 1987 it was first used in an infant by Shrivastava *et al.*[8] Subsequently, a few children, needing for various reasons, an interatrial communication have been treated with this tecnique.[6 9-13]

In this study, of what we believe to be the largest group of patients treated with this method and with the longest follow up, the technique was beneficial and safe in nearly all our patients. It was unsuccessful in two patients:case 10 who had a repeat septostomy and case 14 who had a blade septostomy. In the transposition group the arterial oxygen saturation increased significantly which enabled all seven infants to wait for subsequent Senning or Musterd operations. In the group with complex congenital heart diseases with mitral atresia or stenosis, percutaneous balloon dilatation of the atrial septum was associated with significant decompression of the left atrium in eight out of nine patients, as indicated by the lowering of the transatrial gradient and the increase in arterial oxygen saturation after the procedure.

In the six patients with primary pulmonary hypertension, the creation of the interatrial communication relieved symptoms (no more syncopal episodes or cyanotic spells and improved exercise tolerance), with a moderate drop in the arterial oxygen saturation.

The interatrial communication created in all of our patients was of adequate size. What is more important is that this result, with the exception of three cases mentioned before, was maintained during a mean follow up period of 16·6 months after the procedure. This accords with the findings of previous investigators,[9-13] who also found that the opening did not become smaller even during long periods of follow up. The only exception was in the group of patients with mitral atresia or stenosis. Both our failures, early and late, were encountered in this group. Khan *et al*[5] had a similar experience in a group of 10 patients with mitral atresia who underwent blade septostomy. Four of them, after a mean period of 21 months, needed repeat septostomy because the size of the communication was inadequate. In the nine patients with intact interatrial septum, the creation of a small initial hole by transseptal puncture was uneventful and without any complications. Rao *et al*[23] on the basis of theoretical considerations have suggested that balloons three or four times the size of the patent foramen ovale should be used. Ballerini *et al*[9] have used a modification of the technique by performing a Rashkind septostomy after the initial balloon dilatation, but our data suggest that this may be unecessary. Failure may occur when the atrial septum is very thick,[9,10] no matter what technique is used, and a small percentage of patients will require surgical septostomy.

Hausknecht *et al*[12] and Rotman *et al*[13] were the first to use balloon dilatation of the atrial septum for palliation of two patients with primary pulmonary hypertension. Both were significantly improved and one of them had a successful single lung transplantation 13 months later. As the procedure is not without risks in this setting, particularly when the pulmonary arteriolar resistance is very high, Nihill *et al*[11] recommend that it should be avoided in cases with pulmonary arteriolar resistance of more than 50 units/m^2. None of our patients exceeded this level, and, based on our limited experience, we believe that an atrial opening of 7–8 mm is ideal. This was achieved by initially employing a 13 mm balloon, and after reassessment of haemodynamics the procedure was completed with a 15 mm or 18 mm balloon. Another variable that should be considered is the fall in arterial oxygen saturation. According to Rich *et al*[24] a saturation of less than 72% is associated with high mortality. In our cases we aimed at a systemic oxygen saturation of between 80% and 85%, as did Rotman *et al*,[13] and finally we achieved saturations of 79% to 86%.

In conclusion, balloon dilatation of the atrial septum is an effective and safe procedure for creating long lasting atrial communications that can be used as an alternative to Rashkind's blade septostomy.

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